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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,033	05/11/2001	Pierre Chambon	065691-0222	5081

7590 09/09/2002
Stephen B. Maebius
FOLEY & LARDNER
Suite 500
3000 K Street, N.W.
Washington, DC 20007-5109

EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 09/09/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/853,033

Applicant(s)

CHAMBON ET AL.

Examiner

Celine Qian

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1-61 are pending in the application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 8, 10-15, 33 and 40-52, drawn to a non-human metazoan organism comprising a fusion protein comprising a recombinase and a portion of human nuclear estrogen receptor inserted into one or more chromosomes of the genome, classified in class 800, subclass 18.
- II. Claims 9, 16 and 17, drawn to a non-human metazoan organism comprising a fusion protein comprising a recombinase and a portion of human nuclear estrogen receptor integrated into an extrachromosomal expression vector, classified in class 800, subclass 8.
- III. Claim 25, drawn to a method of preparing a metazoan organism comprising a fusion protein comprising a recombinase and a portion of human nuclear estrogen receptor inserted into one or more chromosomes of the genome by introducing the protein into embryonic stem cells, classified in class 800, subclass 25.
- IV. Claim 26, drawn to a method of preparing a metazoan organism comprising a fusion protein comprising a recombinase and a portion of human nuclear estrogen receptor inserted into one or more chromosomes of the genome by introducing the protein into somatic cells, classified in class 800, subclass 21.
- V. Claim 27, drawn to a method of preparing a metazoan organism comprising a fusion protein comprising a recombinase and a portion of human nuclear estrogen

receptor inserted into one or more chromosomes of the genome by introducing the protein into the embryo, classified in class 800, subclass 25.

- VI. Claim 28, drawn to a method of preparing a metazoan organism comprising a fusion protein comprising a recombinase and a portion of human nuclear estrogen receptor inserted into one or more chromosomes of the genome by nuclear transfer of a somatic cell comprising said protein, classified in class, subclass
- VII. Claims 29, 30, 32 and 36, drawn to a method of conditional recombination by ligand activation, classified in class 800, subclass 24.
- VIII. Claim 31, a method of making a metazoan organism comprising a fusion protein comprising a recombinase and a portion of human nuclear estrogen receptor inserted into one or more chromosomes of the genome by mating and ligand activation, classified in class 800, subclass 22.
- IX. Claim 35 and 57, drawn to a method of analyzing the biological function of a DNA by using a metazoan organism comprising a fusion protein comprising a recombinase and a portion of human nuclear estrogen receptor inserted into one or more chromosomes of the genome, classified in class 800, subclass 3.
- X. Claim 35, drawn to a method of analyzing the biological function of a DNA by using a cell derived from a metazoan organism comprising a fusion protein comprising a recombinase and a portion of human nuclear estrogen receptor inserted into one or more chromosomes of the genome, classified in class 435, subclass 325.

- XI. Claim 37, drawn to a method of screening compounds capable of being used as a medicament that alters the expression of said DNA sequence, classified in class 536, subclass 24.5.
- XII. Claim 37, drawn to a method of screening compounds capable of being used as a medicament that alters the function of said DNA sequence, classified in class 530, subclass 351.
- XIII. Claim 38, drawn to use of a metazoan organism comprising a fusion protein comprising a recombinase and a portion of human nuclear estrogen receptor inserted into one or more chromosomes of the genome for carrying out a spatiotemporally controlled site-specific recombination of DNA in its natural chromatin environment, unclassifiable.
- XIV. Claims 38 and 39, drawn to use of a cell derived from a metazoan organism comprising a fusion protein comprising a recombinase and a portion of human nuclear estrogen receptor inserted into one or more chromosomes of the genome for carrying out a spatiotemporally controlled site-specific recombination of DNA in its natural chromatin environment, classified in class 435, subclass 354.
- XV. Claims 53 and 58, drawn to a method of screening medicaments for the preventive and/or curative treatment of alopecia and/or hyperproliferation of the keratinocytes and/or of inflammatory reactions of the skin by using a transgenic mouse, classified in class 800, subclass 3.

XVI. Claims 54 and 59, drawn to a method of screening compounds for promoting hepatic regeneration by using a transgenic mouse, classified in class 800, subclass 3.

XVII. Claims 55 and 60, drawn to a method of screening compounds for treating/preventing obesity and/or diabetes by using a transgenic mouse, classified in class 800, subclass 3.

XVIII. Claims 56 and 61, drawn to a method of screening compounds for treating/preventing skin cancer by using a transgenic mouse, classified in class 800, subclass 3.

Claims 1-7, 18 and 20 embrace the inventions of Groups I and II, and will be examined in so far as it reads on the elected subject matter.

The inventions are distinct, each from the other for following reasons.

The inventions of Groups I and II are patentably distinct because the inventions are drawn to materially distinct compositions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different function, and different effects. The products of Groups I and II have different chemical structures, are made by different methods, and can be used in different methods which require different technical considerations and materially different reagents. Therefore, the inventions of Groups I and II are patentably distinct.

The inventions of Groups III-XVIII are patentably distinct from each other because the inventions are drawn to methods that require different starting material and modes of operation.

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Each method involves different steps, and constitutes patentably distinct invention, each with a distinct purpose and further comprising distinct methodologies and using different products.

Therefore, the inventions of Groups III-XVIII are patentably distinct.

The inventions of Groups I, II and Groups III-XVIII are patentably distinct from each other because they are drawn to inventions that are not directly related. Inventions I and III-VI and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the transgenic metazoan organism of Group I can be made by different process as recited in the methods of Groups III-VI and VIII. Therefore, the inventions of Group I and III-VI, and VIII are patentably distinct.

Inventions I and VII, IX, XI-XIII, XV-XVIII are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the transgenic metazoan organism of Group I can be used in different process as recited in methods of Groups VII, IX, XI-XIII, XV-XVIII.

Therefore, the inventions of Groups I and VII, IX, XI-XIII, XV-XVIII are patentably distinct.

The inventions of Groups I is not required in the method of Groups X and XIV, and the inventions of Group II is not required in the method of Groups III-XVIII. Therefore, the inventions of Groups I, II and Groups III-XVIII are patentably distinct from each other.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. A search of the subject matter of one invention would not be co-extensive with a search of the other invention, and therefore the search would be burdensome. Each invention is capable of supporting a separate patent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.
August 27, 2002


TERRY MCKELVEY
PRIMARY EXAMINER